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Revision Number 0

Section 1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product Code(s) OCUK707300/707350

Product Name Ortho BioVue® System (Poly Cassette)

Synonyms Anti-Human Globulin
Anti-IgG, -C3d; polyspecific
(Rabbit and Murine Monoclonal) (Green)
Ortho BioVue® System
(Poly Cassette)

Pure substance/mixture Mixture

Contains 1-Imidazole.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
Ortho-Clinical Diagnostics	Ortho-Clinical Diagnostics, Inc.
1500 Boulevard Sébastien Brant	1001 US Highway 202
B.P. 30335	Raritan, NJ 08869

67411 Illkirch
CEDEX, France**For further information, please contact**

E-mail Address UK - uk hotline@orthoclinicaldiagnostics.com
France - hotlinefrance@orthoclinicaldiagnostics.com
Germany - ocdtechsupport-de@orthoclinicaldiagnostics.com
Italy - italianhl@orthoclinicaldiagnostics.com
Nordic - nordichotline@orthoclinicaldiagnostics.com
Poland - service_pl@pl.diasorin.com
Portugal - port_ocdhotline@orthoclinicaldiagnostics.com
Irish Republic - uk hotline@orthoclinicaldiagnostics.com
Spain - spanishhotline@orthoclinicaldiagnostics.com

1.4. Emergency telephone number

Emergency Telephone Number **Transportation Emergencies:**
US Telephone Number: (800) 424-9300
International and Maritime Telephone Number: +1 (703) 527-3887

US:
(800) 421-3311

Europe	UK 0 800 895963 France 03 88 65 47 33 Germany 0 800 181 48 97 Italy 800 87 06 55 Nordic 00 800 08372560 Poland 48 (22) 223 62 65 Portugal 0 800 833143 Irish Republic 00 800 08372560 Spain 900 97 33 25
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Reproductive Toxicity	Category 1B
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Physical Hazards

None

2.2. Label Elements



Signal Word

Danger

Hazard Statements

H360 - May damage fertility or the unborn child

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves, Eye Protection

P308 + P313 - IF exposed or concerned: Get medical advice/ attention

P405 - Store locked up

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other information

This product contains animal blood derivatives. No known test method can offer complete assurance that products derived from animal blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.

Section 3. Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight %	EU - GHS Substance Classification	REACH No.
Bovine Serum Albumin (BSA)	232-936-2	9048-46-8	1		No data available
1-Imidazole	206-019-2	288-32-4	0.43	Acute Tox. 4 (H302) Skin Corr. 1C (H314) Repr. 1B (H360D)	No data available
Hydrochloric Acid	231-595-7	7647-01-0	0.386	Skin Corr. 1A (H314) STOT SE 3 (H335) Press. Gas Acute Tox. 3 (H331)	No data available
Sodium azide	247-852-1	26628-22-8	0.0967	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1	No data available

				(H400) Aquatic Chronic 1 (H410)	
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For the full text of the H-Statements mentioned in this Section, see Section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Section 4. First aid measures

4.1. Description of first-aid measures

Eye Contact	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if irritation occurs.
Skin Contact	Wash skin with soap and water. Get medical attention if symptoms occur.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.
Inhalation	Move to fresh air.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects No information available.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases
None known.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

Advice for emergency responders

For personal protection see section 8.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Wipe up with absorbent material (e.g. cloth, fleece). Pick up and transfer to properly labeled containers.

Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink.

6.4. Reference to other sections

Personal protection equipment (PPE) - Refer to Section 8. Disposal - Refer to Section 13.

Section 7. Handling and storage

7.1. Precautions for Safe Handling

Handling

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Store according to label instructions. Store locked up.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Risk Management Measures

The information required is contained in this Safety Data Sheet

Other Guidelines

No information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical Name	EU	The United Kingdom	France	Spain	Germany
Hydrochloric Acid 7647-01-0	TWA 5 ppm TWA 8 mg/m ³ STEL 10 ppm STEL 15 mg/m ³	STEL: 5 ppm STEL: 8 mg/m ³ TWA: 1 ppm TWA: 2 mg/m ³	STEL: 5 ppm STEL: 7.6 mg/m ³	STEL: 10 ppm STEL: 15 mg/m ³ TWA: 5 ppm TWA: 7.6 mg/m ³	TWA: 2 ppm TWA: 3.0 mg/m ³ Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m ³ TWA: 3 mg/m ³
Sodium azide	S*	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³	S*	TWA: 0.2 mg/m ³

26628-22-8	TWA 0.1 mg/m ³ STEL 0.3 mg/m ³	TWA: 0.1 mg/m ³ Skin	STEL: 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	Ceiling / Peak: 0.4 mg/m ³
Component	Italy	Portugal	The Netherlands	Finland	Denmark
Hydrochloric Acid 7647-01-0 (0.386)	TWA: 5 ppm TWA: 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³	STEL: 10 ppm STEL: 15 mg/m ³ Ceiling: 2 ppm TWA: 5 ppm TWA: 8 mg/m ³	STEL: 15 mg/m ³ TWA: 8 mg/m ³	STEL: 5 ppm STEL: 7.6 mg/m ³	Ceiling: 5 ppm Ceiling: 8 mg/m ³
Sodium azide 26628-22-8 (0.0967)	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	STEL: 0.3 mg/m ³ Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm TWA: 0.1 mg/m ³	Skin STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ Skin
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Hydrochloric Acid 7647-01-0	STEL 10 ppm STEL 15 mg/m ³ TWA: 5 ppm TWA: 8 mg/m ³	STEL: 4 ppm STEL: 6 mg/m ³ TWA: 2 ppm TWA: 3 mg/m ³	STEL: 10 mg/m ³ TWA: 5 mg/m ³	Ceiling: 5 ppm Ceiling: 7 mg/m ³	TWA: 8 mg/m ³ TWA: 5 ppm STEL: 10 ppm STEL: 15 mg/m ³
Sodium azide 26628-22-8	Skin STEL 0.3 mg/m ³ TWA: 0.1 mg/m ³	STEL: 0.4 mg/m ³ TWA: 0.2 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures Showers.
Eyewash stations.
Ventilation systems.

Personal protective equipment

Eye Protection Safety glasses with side-shields.
Skin and Body Protection Impervious clothing.
Hand Protection Impervious gloves.
Respiratory Protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State Liquid.
Odor None.
Appearance Green.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	6.8 - 7.2	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Relative Density	No data available	None known

Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
Explosive Properties	No data available	
Oxidizing Properties	No data available	

9.2. Other information

VOC Content (%)	No information available
Flammability Limits in Air	No data available

Section 10. Stability and reactivity

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Heat. Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

None under normal use.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Product Information

Inhalation

No known effect based on information supplied.

Eye Contact

No known effect based on information supplied.

Skin Contact

No known effect based on information supplied.

Ingestion

No known effect based on information supplied.

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
1-Imidazole	= 220 mg/kg (Rat)		
Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	-

Sensitization

No information available

Mutagenic Effects

No information available.

Carcinogenic Effects

Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity

May damage fertility or the unborn child.

Developmental Toxicity

No information available.

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Other Adverse Effects No information available.
Aspiration Hazard No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity Effects

The environmental impact of this product has not been fully investigated. Contains a substance which is harmful to the aquatic environment with long lasting effects at very low concentrations.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
1-Imidazole	EC50 72 h: = 130 mg/L (Desmodesmus subspicatus) EC50 96 h: = 82 mg/L (Desmodesmus subspicatus)		EC50 = 1200 mg/L 17 h EC50 = 231 mg/L 30 min	EC50 48 h: = 341.5 mg/L (Daphnia magna)
Sodium azide		LC50 96 h: = 0.8 mg/L (Oncorhynchus mykiss) LC50 96 h: = 0.7 mg/L (Lepomis macrochirus) LC50 96 h: = 5.46 mg/L flow-through (Pimephales promelas)		

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Chemical Name	Log Pow
1-Imidazole	-0.02

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from Residues / Unused Products Dispose of in accordance with local regulations.

Contaminated Packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Marine Pollutant	None.
14.6. Special Provisions	None.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

RID

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Environmental hazard	None.
14.6. Special Provisions	None

ADR

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	None.
14.4. Packing Group	Not regulated.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

IATA/ICAO

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

Section 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Candidate List of Substances of Very High Concern for Authorization

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

EUH032 - Contact with acids liberates very toxic gas
H300 - Fatal if swallowed
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H331 - Toxic if inhaled
H360D - May damage the unborn child
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Key literature references and sources for data

www.ChemADVISOR.com/

Issuing Date	19-Dec-2019
Revision Date	19-Dec-2019
Revision Note	Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet